

Notice of Public Hearing

Pursuant to Section 22215 of Public Act 306 of 1969, as amended, the Michigan Department of Community Health (MDCH) will hold a hearing on Certificate of Need (CON) Review Standards.

Date: Tuesday, August 5, 2008
Time: **10:30AM**
[Megavoltage Radiation Therapy (MRT) Services/Units]
Location: Capitol View Building
201 Townsend Street, 1st floor
MDCH Conference Center Room C
Lansing, MI 48913

MRT Services/Units

The proposed CON Review Standards for MRT Services/Units are being reviewed and modified to include, but are not limited to, the following:

1. Modified the definition of “heavy particle accelerator” to specifically include carbon ions.
2. Added definitions for “high MRT (HMRT) unit” and “hospital MRT service” for purposes of Section 10.
3. Modified the definitions for “non-special MRT unit” and “special purpose MRT unit.”
4. Removed references to heavy particle accelerator under sections 5 and 6 since they would no longer be considered special purpose MRT units.
5. Added a new Section 10, “Requirements for approval – applicants proposing to initiate an MRT service utilizing an HMRT unit.” This new section includes the following provisions:
 - The applicant shall be a single legal entity authorized to do business in Michigan.
 - The applicant shall be a collaborative consisting of, at a minimum, at least 40% of all Michigan hospital MRT services with more than 30,000 equivalent treatment visits (ETVs) performed in the most recent 12-month period of data available to the Department.
 - The collaborative shall include hospital MRT services from more than one planning area from either or both of the following: i) the participating services under subsection (b) (those above 30,000 ETVs); ii) hospital MRT services with the highest number ETVs in a planning area based on the most recent 12-month period of data available to the Department.
 - MRT services that are already part of a collaborative application under the section for an MRT service utilizing an HMRT unit or part of an existing collaborative utilizing an HMRT unit approved under the new section shall not be included in a new application.
 - The applicant shall provide documentation of its process, policy, and procedures, acceptable to the Department, that allows any other interested entities to participate in the collaborative utilizing an HMRT unit.
 - The applicant shall provide an implementation plan, acceptable to the Department, for financing and operating the proposed MRT service utilizing an HMRT unit which includes how physician staff privileges, patient review, patient selection, and patient care management shall be determined.
 - MRT services utilizing an HMRT unit shall be provided to adult and pediatric patients.
 - The MRT service utilizing an HMRT shall have simulation capabilities available for use in treatment planning.
 - MRT services utilizing an HMRT unit demonstrate compliance with the requirements of Section 4(3).

- Additional project delivery requirements for MRT services utilizing an HMRT unit have been included: 1) All patients treated shall be evaluated for potential enrollment in research studies focusing on the applicability and efficacy of utilizing an HMRT unit to treat site specific cancer tumors. A summary of the information shall be provided to the Department. 2) The MRT service utilizing an HMRT unit will provide, on an annual basis, the Department with reports designed to assess the affordability, quality, and accessibility of the MRT service utilizing an HMRT unit. The report shall include annual updates to the information provided in subsections 10(e), (f), and (g). 3) As a condition of approval, an MRT service utilizing an HMRT unit shall agree that upon review of the report submitted under subsection (b), the Department may order changes with regard to the provision of the service.
6. Replaced reference to heavy particle accelerator with HMRT units where applicable in the project delivery requirements and Table 1 in Section 13.
 7. Updated the following project delivery requirement as shown: “All MRT treatments shall be performed under the supervision of a radiation oncologist and at least one radiation oncologist will be IMMEDIATELY AVAILABLE ~~on-site at the geographic location of the unit~~ during the operation of the unit(s).” Immediately available is already defined in the standards as “continuous availability of direct communication with the MRT unit in person or by radio, telephone, or telecommunication.”
 8. Other technical changes.

In addition to comments on the draft language, the Department and CON Commission is soliciting public comment on an alternative methodology utilizing ETVs (refer to “Alternative Methodology” document for potential language) or other approaches vs. a percentage for participation in an application to initiate an MRT service utilizing an HMRT unit.



Oral or written comments may be presented in person at the hearing on Tuesday, August 5, 2008, or submitted in writing via online submission at www.michigan.gov/mdch/0,1607,7-132-2945_5106_5409-196938--,00.html, no later than 5:00 p.m., August 12, 2008. If your comment is in written form, please provide a copy to the court reporter at the conclusion of your testimony. If you have any questions or concerns, please contact Andrea Moore at 517-335-6708.

Be sure all cellular telephones and pagers are turned off or set to vibrate during the hearing.

The hearing location is accessible for persons with physical disability. Interpreters will be available for the hearing impaired, if requested, seven days in advance.

07/25/08